EXHIBIT K

FDA to Approve Shared System REMS for TIRF Products

Dec 29, 2011, 12:55 ET from U.S. Food and Drug Administration

SILVER SPRING, Md., Dec. 29, 2011 /PRNewswire-USNewswire/ --The U.S. Food and Drug Administration today approved a single shared Risk Evaluation and Mitigation Strategy (REMS) for the transmucosal immediate-release fentanyl (TIRF) products. This new shared system will replace the individual REMS and allow prescribers and pharmacies to enroll into just one system, easing the burden on the health care system.

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TIRF medicines, which include the brand-name drugs Abstral, Actiq, Fentora, Lazanda, and Onsolis, are narcotic pain medicines called opioids used to manage pain in adults with cancer who routinely take other opioid pain medicines around-the-clock.

The shared system strategy, called the TIRF REMS Access Program, will be used by all sponsors of TIRF products and is expected to ease the burden on the health care system. The program will begin in March, 2012. Until that time, prescribers, patients, and pharmacies should continue to enroll in the individual REMS programs.

"This TIRF REMS will ensure safe use and access to these drugs for patients who need them," said Janet Woodcock, M.D., director of the FDA's Center for Drug Evaluation and Research. "We have worked with the sponsors of both the innovator and generic drugs to

develop this single, shared system that will streamline the process and decrease the burden of the REMS on the health care system."

The goals of the TIRF REMS Access Program are to ensure patient access to important medications and mitigate the risk of misuse, abuse, addiction, overdose and serious complications due to medication errors by:

- prescribing and dispensing TIRF medicines only to appropriate patients, including use only in opioid-tolerant patients
- preventing inappropriate conversion between fentanyl products
- preventing accidental exposure to children and others for whom TIRF medicines were not prescribed
- educating prescribers, pharmacists, and patients on the potential for misuse, abuse, addiction, and overdose.

Several TIRF products already have an individual REMS in place. Prescribers and pharmacies already enrolled in an individual REMS program for at least one TIRF medicine will automatically be transitioned to the shared TIRF REMS Access program.

Health care professionals who prescribe TIRF medicines that will only be used in an inpatient setting (hospitals, hospices, or long-term care facilities) will not be required to enroll in the TIRF REMS Access program. Similarly, patients who receive TIRF medicines in an inpatient setting are not required to enroll in the program. Long term care and hospice patients who obtain their medications from outpatient pharmacies must still be enrolled.

For more information:

TIRF REMS Questions and Answers

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics,

dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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